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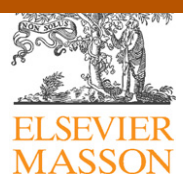

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ORIGINAL ARTICLE

Does hyperflex total knee design improve postoperative active flexion?

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KEYWORDS
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Summary
Introduction: The rotating platform flexion (RPF) Sigma total knee prosthesis (DePuy; Warsaw, Indiana) was designed for maintaining the contact of the condyles with their corresponding tibial plateau throughout the high-flexion range. However, this requires an additional 3-mm bone cut of the posterior condyles. Compared to the conventional design, this modification is intended to improve the flexion range. This hypothesis was tested by studying the increase in flexion (flexion gain, range of motion [ROM], active flexion) of 59 consecutive patients who had received the hyperflex design implant (RPF), whose preoperative mobility values were retrospectively compared to these same values in another 59 consecutive matched patients who had received an implant with the conventional design of the same implant (rotating platform [RP]) between June 2005 and June 2006. Postoperative mobility was measured visually with a goniometer.
Patients and methods: Only osteoarthritic knees were eligible to be included. Knees with more than 20° flexion contracture or less than 90° flexion, and patients with a body mass index (BMI) greater than 30 were excluded. Both groups were comparable with regard to age, preoperative mobility values, and BMI. The sex ratio differed significantly, but preoperative mobility did not differ significantly in male and female patients in the RP and in the RPF groups. The difference in sex ratio did not appear to be a bias influencing preoperative mobility.
Results: Overall, the flexion gain was correlated to preoperative flexion ($r = -0.75$, $p < 0.001$). The flexion gain in the RPF group was significantly greater than in the RP group (13 + -20 versus 6 + -13; $p = 0.02$) as was the ROM gain ($10 \pm 17°$ versus $4 \pm 12°$; $p = 0.02$). However, the one-year active mean flexions were not significantly different ($118 \pm 14°$ versus $116 \pm 6°$; $p = 0.47$). In

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patients whose preoperative flexion was less than 120° (18 and 27 RPF prostheses), the flexion and ROM gains were significantly greater in the RPF group (23 ± 16° versus 14 ± 16°; $p = 0.03$ and 26 ± 18° versus 17 ± 9°; $p = 0.05$), and the mean one-year active flexion was also greater in the RPF group (124 ± 13° versus 116 ± 8°, $p = 0.02$). In patients with more than 120° of preoperative flexion, the flexion and ROM gains and the final mean flexions in both groups were comparable. In particular, there were nine patients in the RP group and ten patients in the RPF group whose flexion decreased.

Conclusion: Thus, the Sigma RPF prosthesis provided a significant additional flexion gain in patients with 90—120° preoperative flexion, and less than 20° flexion contracture. Patients with a preoperative flexion greater than 120° were exposed to a decrease in flexion range whichever implant was used, RP or RPF.

Level of evidence: Level 3, therapeutic study.

Introduction

Knee prostheses have the disadvantage of not restoring normal mobility in flexion, for which a number of causes have been advanced. The postoperative flexion range depends on the preoperative flexion range [1]. The quality of the surgical act is also a determining factor in the result, notably in the ligament balance and the quality of the bone cuts [2,3]. However, even when the conditions for an optimal result are present, the final mean flexion only rarely exceeds 120° [4]. Active flexion is limited by impingement between the posterior edge of the tibial plateau and the posterior femoral cortex, with more or less rapid onset depending on the prosthetic kinetics [2,5].

The prosthesis design has been modified to delay this impingement and preserve joint contact in high flexion. These modifications extend the posterior area of the condyle surface, which requires thicker metallic posterior condyles, requiring an additional posterior bone cut compared to the conventional design [6].

It was therefore hoped that hyperflexion would result when all the favorable factors were combined: absence of preoperative stiffness and suitable operative technique. We tested this hypothesis by comparing two groups of patients with no preoperative stiffness who were operated on by six senior surgeons. The first group of patients received an implant with a conventional design (Sigma press fit condylar [PFC] rotating platform [RP]; DePuy; Warsaw, Indiana), and the second group using the hyperflex design (Sigma rotating platform flexion [RPF] prosthesis). The only difference in design between the two implants was 3-mm greater thickness of the posterior condyles in the RPF design compared to the conventional design. The clinical results at one year were examined in these patients who had gonarthrosis with no postoperative complications that could compromise rehabilitation.

Patients and methods

A multicenter study was organized in four centers with extensive surgical implant activity (more than 50 knee implants per year for each surgeon). The study included patients from 45 to 85 years of age with a body mass index (BMI) less than 30, with gonarthrosis, excluding stiff knees (flexion contracture over 20° and/or preoperative flexion less than 90°) and frontal deformities greater than 15°. Only patients with no postoperative complications that could alter the mobility results were retained. Consequently, none of the patients in this series suffered from infection or surgically treated hematoma and no symptomatic phlebitis extended above the popliteal area.

From June 2005 to June 2006, 61 consecutive patients were included and received Sigma cemented three-compartment PFC prostheses. From June 2006 to June 2007, 63 patients were included consecutively and received a cemented Sigma RPF three-compartment prosthesis. There were 42 valgus knees and 19 valgus knees in the RP prosthesis group (mean HKA, 178 ± 9°) and 47 valgus knees and 16 valgus knees in the RPF prosthesis group (mean HKA, 177 ± 8°). The implantation technique comprised a horizontal tibial cut perpendicular to the mechanical axis, with the 3° slope included in the insert. With these moderate deformities, we did not perform any particular ligament release. The femoral components were positioned with 3° external rotation in relation to the posterior bicondylar line. The ligaments were balanced so as to obtain complete extension at the end of the procedure with equal flexion and extension gaps. All the inserts were mobile inserts, posterior-stabilized rotating platforms. Rehabilitation with continuous passive motion began as early as the first or second postoperative day. The patients were admitted to a rehabilitation center for a variable duration, 15—45 days, after being discharged from the hospital. The clinical and radiographic results at one year were recorded, with visual measurement of mobility using a goniometer. The clinical results were recorded prospectively using the Feller patellar score [7] and the IKS score [8] for overall knee function.

All the patients included in the study were seen at follow-up. Mobility was assessed in terms of flexion gain (postoperative flexion minus preoperative flexion) or extension gain (preoperative flexion contracture minus final residual flexion contracture), range of motion gain, and the absolute value of active flexion. The range of motion was calculated for each knee by the difference between the flexion angle and the extension angle. A weightbearing goniometry was performed at the end of rehabilitation to measure the postoperative mechanical axis. It was 180 ± 3°

Table 1 Demographic data of the two patient groups with *p*-value for the comparison. The proportion of females was significantly higher in the RP group ($p = 0.02$), but the preoperative mobility values were comparable.

	Age	Sex	Preop flexion	Preop extension	Charnley	Patellar score	Knee score	Function score	BMI
RP ($n = 59$)	74 ± 7	44F/15M	118 ± 14	3 ± 5	40A/18B/1C	16 ± 7	35 ± 17	50 ± 16	28±4
RPF ($n = 59$)	71 ± 10	28F/31M	116 ± 16	4 ± 5	33A/25B/1C	16 ± 7	38 ± 18	46 ± 22	29±4
p	0.06	0.01	0.47	0.27	0.3	1	0.35	0.26	1

RP: rotating platform; RPF: rotating platform flexion.

Table 2 Demographic data of the two patient groups with preoperative flexion between 90 and 120°.

	Age	Sex	Preop flexion	Preop extension	Charnley	Patellar score	Knee score	Function score	BMI
RP ($n = 18$)	73 ± 6	7F/11M	101 ± 9	3 ± 5	14A/4B	16 ± 8	93 ± 6	90 ± 16	28 ± 3
RPF ($n = 27$)	74 ± 6	13F/14M	101 ± 8	5 ± 5	22A/4B/1C	14 ± 7	89 ± 16	88 ± 15	29 ± 5
p	0.6	0.4	0.99	0.19	0.3	0.08	0.31	0.67	1

RP: rotating platform; RPF: rotating platform flexion.

in the RP prosthesis group and 181 ± 2° in the RPF prosthesis group.

These two groups, made up prospectively, were compared retrospectively and non-randomly. Estimating the goniometer measurement error at ±5°, we attempted to demonstrate a difference of 10° or more, i.e., greater than or equal to the maximum estimated measurement error, in flexion between the two groups of patients at one year. Based on a mean expected flexion of 110 ± 20° and considering a 5% risk of a false-positive result and a 95% statistical power, we estimated the number of patients necessary in a unilateral test to be 50 in each group. Adding 20% for possible exclusions related to unforeseen postoperative events (complications, death of older patients, patients lost to follow-up), 60 patients needed to be included in each group.

The study of the characteristics of the two patient populations included prospectively showed that the proportion of females was higher in the RP prosthesis group. We therefore sought to determine whether the difference in the sex ratio amounted to a detection bias for the comparison. Although the female and male populations had comparable characteristics in the RP prosthesis group, they had different preoperative mobilities in the RPF prosthesis group. The women's group had greater preoperative flexion contracture (7 ± 8°) than the men's group (3 ± 5°; $p = 0.02$). A posteriori, six additional patients with flexion contracture equal to 20° had to be excluded to make up homogenous groups paired based on preoperative mobility, which then became the basis of the comparison whose results are presented below. Finally, each group included 59 patients (Table 1). The only differences concerned the smaller proportion of women in the RPF prosthesis group (74 versus 47%; $p = 0.01$) and their higher age than the RP group men (76 ± 5 years versus 70 ± 8 years; $p = 0.01$), but they had preoperative mobility values that were comparable to those of the men in both groups.

As in the study conducted by the promotors [9], the groups were compared based on preoperative flexion (less than or greater than 120°). There were 18 patients with a RP prosthesis and 27 patients with a RPF implant who had preoperative flexion less than 120°. Although smaller, these two subpopulations were comparable in terms of sex ratio, age, and preoperative mobility (Table 2).

The means were compared using the Student *t*-test for unpaired series (with the test adapted to small sample sizes when there were fewer than 30 members in a group) and the proportions were compared using the chi-square test (with Yates correction of the proportions less than 5%). Pearson correlation tests were used to correlate the flexion gains with the degree of preoperative flexion.

Table 3 Results of the comparison of postoperative mobility in the overall series.

	Postoperative active flexion	Gain in active extension	Gain in active flexion	Gain in range of motion
RP ($n = 59$)	123 ± 10	2 ± 5	6 ± 13	4 ± 12
RPF ($n = 59$)	126 ± 12	3 ± 5	13 ± 20	10 ± 17
p	0.14	0.8	0.02	0.02

RP: rotating platform; RPF: rotating platform flexion.

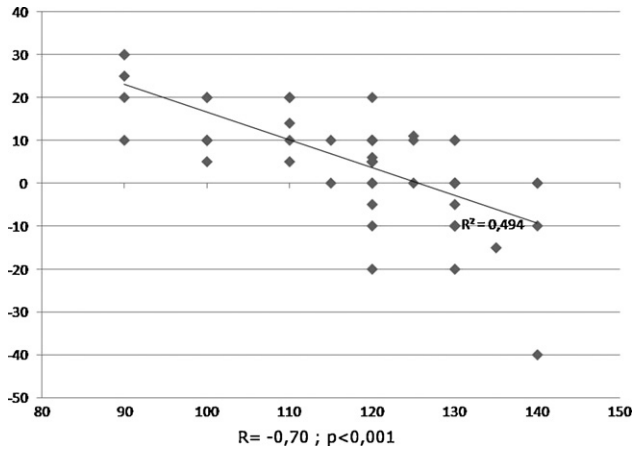

Figure 1 Gain in flexion in degrees (*y*-axis) expressed as a function of the degree of preoperative flexion (*x*-axis) in the RP prosthesis group (with the relation: $y = -0.7x + 88$).
0.494: $R = -0.70$; $p < 0.001$; −50, −40, etc.

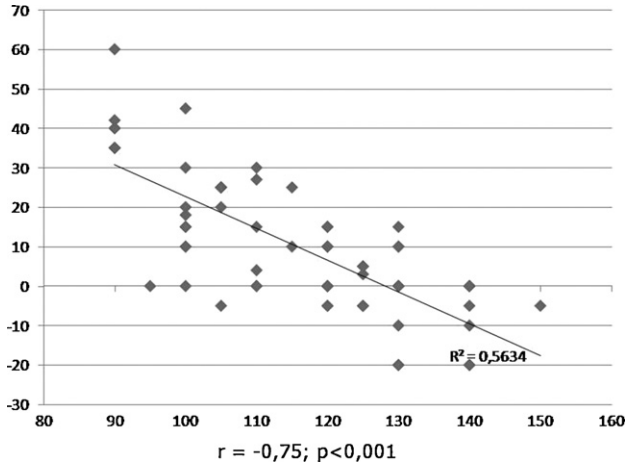

Figure 2 Gain in flexion in degrees (*y*-axis) expressed as a function of the degree of preoperative flexion (*x*-axis) in the RPF prosthesis group (with the relation: $y = -75x + 95$).
0.5634: $R = -0.75$; $p < 0.001$; −30, −20, etc.

Results

At one year, all the X-rays showed stable implants with no radiolucent line identifying the cement—bone interface.

In the two groups of 59 implants, the flexion gain was strongly and negatively correlated with the degree of preoperative flexion ($r = -0.7$; $p = 0.001$), indicating that patients with very good preoperative flexion could lose flexion no matter which implant was used (Figs. 1 and 2). Overall, the RPF implants provided significantly greater gain in range of motion than the RP prostheses ($10 \pm 17^\circ$ versus $4 \pm 12^\circ$; $p = 0.02$) as well as a flexion gain that was also significantly higher than with the RP prostheses ($13 \pm 20^\circ$ versus $6 \pm 13^\circ$; $p = 0.02$). On the other hand, postoperative flexion in absolute values was equivalent ($118 \pm 14^\circ$ versus $116 \pm 6^\circ$; $p = 0.47$) (Table 3). The mean IKS knee and function scores and the patellar score at one year did not differ ($p = 0.1$, $p = 1$ and $p = 0.7$, respectively). Ten points were gained for the mean patellar score and 52 and 43 points for the mean IKS knee and function scores, respectively. Most particularly, the patellar and IKS scores for women who had received a RPF prosthesis, which were significantly lower than men's preoperatively, reached the men's scores at one year after surgery.

The flexion gain was greater in patients with preoperative flexion less than 120°. In this category of patients (Table 4), the RPF implant provided a mean additional flexion gain of 9° ($23 \pm 16^\circ$ for the RPFs versus $14 \pm 9^\circ$ for the RPs; $p = 0.03$) and an additional gain in range of motion of 9° ($26 \pm 18^\circ$ for the RPFs versus $17 \pm 9^\circ$ for the RPs; $p = 0.05$). Moreover, the final flexion of the RPF patients was also significantly higher than the final flexion of the RP patients ($124 \pm 13^\circ$ for the RPFs versus $116 \pm 8^\circ$ for the RPs; $p = 0.02$).

On the other hand, there was no significant difference between the gains in flexion, range of motion, and the mean final active flexion values in patients with more than 120° of preoperative flexion, whether they had received a RP prosthesis or a RPF prosthesis ($p = 1.0$, $p = 0.72$, and $p = 0.39$, respectively). In particular, nine patients with an RP prosthesis (50%) and ten patients with an RPF prosthesis (37%) showed decreased flexion ($p = 0.7$).

Discussion

The prostheses designed for hyperflexion should theoretically improve the hyperflexion conditions when this is possible. The hyperflexion conditions seem to be related to the patient (preoperative mobility) and surgical technique (tibial slope, posterior condylar offset) more than to the prosthesis design. Most certainly, a posterior stabilization cam seems to improve the posterior condylar roll-back, which itself favors the high-flexion ranges because it delays the posterior impingement between the posterior edge of the tibial plateau and the posterior cortex of the femur [2,10]. However, the two implants compared in this study were equipped with this feature.

It therefore seems that posterior extension of the condylar joint surfaces may also delay posterior impingement between the femur and the posterior edge of the tib-

Table 4 Results of the comparison of postoperative mobility in the patients with preoperative flexion less than 120°.

	Postoperative active flexion	Gain in active extension	Gain in active flexion	Gain in range of motion
RP ($n = 18$)	116 ± 8	3 ± 4	14 ± 9	17 ± 9
RPF ($n = 27$)	124 ± 13	4 ± 6	23 ± 16	26 ± 18
p	0.02	0.53	0.03	0.05

RP: rotating platform; RPF: rotating platform flexion.

ial plateau, because the RPF prostheses have significantly improved the active flexion gain and the active flexion range of motion in patients with preoperative flexion between 90 and 120°. It is normal for this effect to disappear beyond 120° because it is partially a passive flexion sector [11] and the room for progression of active mobility is limited. However, of the knees with preoperative active flexion greater than 120°, there are flexion decreases with both implants, a possibility that these patients should be informed of.

In patients with preoperative flexion less than 120°, the final flexion of the patients who had received RPF prostheses exceeded the final flexion of patients receiving an RP implant by a mean 8°, close to the maximum margin of error estimated (10°), which may well indicate that this gain can indeed be taken into account because it is not likely that the measurement error was maximum in all cases. With the same methodology, other authors have reported improvements in flexion using hyperflex implants. As promotors of the device, Gupta et al. [9] reported similar results, with a mean 10° improvement in flexion compared to the RP implant results. On the other hand, the prospective and randomized study conducted by Kim et al. [12] with another type of implant designed for hyperflexion showed no gain in flexion compared to the conventional design, but the preoperative mobility values were already excellent and their results are therefore in agreement with those from our patients who had preoperative flexion greater than 120°.

Finally, contrary to Ritter and Campbell [13], this additional flexion gain does not seem to have significantly improved the postoperative knee or function score, which confirms the observations of Massin et al. [14]. The scores used are probably not sufficiently discriminating and an evaluation with quality-of-life scores could give different results. It is interesting to note, however, that the increase in flexion did not affect the patellar score.

This study has a certain number of limits. As in the study by the promotors of the implant [9], the patients were not randomized. However, these were consecutive patients whose surgery dates were grouped over a short period of time, with a greater probability, therefore, that the surgical techniques were homogenous. In addition, the clinical assessment was not done blindly and most of the patients were examined by the operating surgeon, which can introduce an evaluation bias. Third, there was a sex ratio difference between the two groups, but this difference was absent in the group of patients with preoperative flexion less than 120°. Finally, this study only reports results at one year. Although it seems that mobility does not evolve, or very little, beyond this point in time [15,16], the long-term effect of these high flexion values on the polyethylene and on fixation remains to be clarified with longer follow-up.

In conclusion, subject to these limitations and in absence of substantial preoperative flexion contracture (20° or more), it seems that the design modifications in knee prostheses to extend the joint contact in the high-flexion range improves the gain in active flexion in patients with preoperative flexion between 90 and 120°. However, for patients with high preoperative flexion, the knee implant, however it is designed, remains likely to reduce flexion range of motion.

Conflict of interest statement

PM, CF, TP, PS, CF, PM. Clinical trial: co-investigators, non-principal investigators, collaborators in the study for DePuy France.

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